Rational Pharmaceutical Management Plus
Technical Assistance to support MSH/RPM Plus Activities in Rwanda under the Presidential Initiative for AIDS Relief: Trip Report

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Contents

Acronyms

ARV	Antiretroviral
CAMERWA	Centrale d'Achat de Medicaments Essentielles au Rwanda
ART	Antiretroviral treatment
CHUK	Centre Hospitalier Universitaire de Kigali
CHB	Centre Hospitalier de Butare
CHU	Centre Hospitalier Universitatire
DSS	Direction de Soins de Sante
CNLS	Comité National pour la Lutte contre le SIDA
DOP	Direction de la Pharmacie
TRAC	Treatment and Research AIDS Center
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
MCUP	
HMK	
LNR	Laboratoire Nationale de Reference
M&E	Monitoring and Evaluation
MAP	
MIS	Management Information Systems
MOH	Ministry of Health
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
GF	Global Fund
NRL	National Reference Laboratory
PNLS	Programme Nationale pour la Lutte Contre de SIDA
RPM	Rational Pharmaceutical Management Project
PEPFAR	Presidential Initiative for AIDS Relief
RPM Plus	Rational Pharmaceutical Management Plus Program
SIS	Système d'Information Sanitaire
TB	Tuberculosis
TRAC	Treatment and AIDS Research Center
USAID	United States Agency for International Development
WHO	World Health Organization

Background

Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus (RPM Plus) Program has received funds from USAID Mission in Rwanda under PMTCT and Presidential Emergency Plan for AIDS Relief to assist the Mission in supporting the national scale up of HIV/AIDS programs, in the area of HIV/AIDS-related commodities management. USAID is supporting RPM Plus in order to strengthen the pharmaceutical and laboratory management systems in Rwanda, at central and facility levels, in cooperation with the MOH and CAMERWA. In previous visits RPM Plus has conducted general and specific assessments to identify and strategize the major areas requiring technical assistance, by RPM Plus staff and external consultants. RPM Plus has also built a network with key local stakeholders involved in the pharmaceutical and laboratory sectors, as well as with other agencies working in the country, to coordinate activities and to develop an agreed action plan. RPM Plus has now a well established office in Kigali, staffed with local technical and administrative personnel.

Purpose of Trip

The purpose of the trip was to provide technical support to the new MSH/Rwanda staff for a range of activities under the RPM Plus/MSH activities for PEPFAR 1.5 and 2.0.

Scope of Work

The scope of work for Christine Onyango was as follows:

- Brief the USAID/Rwanda mission as requested
- Provide technical support to Hare Ram Bhattarai, MSH/RPM Plus , who will be working in Rwanda in support of PEPFAR activities from September 12-24, 2004
- Coordinate activities related to MSH/RPM Plus work in management information systems
- Provide support to MSH/RPM Plus Rwanda staff for the organization of a stakeholder meeting to develop standard operating procedures (SOPs) for the pharmaceutical sector.
- Provide technical support to MSH/RPM Plus Rwanda staff for laboratory management and training activities
- Provide technical assistance for the organization of training module on pharmaceutical management to be integrated in TRAC activities.
- Provide technical assistance in the revision of tools to assess capacity of ART sites for pharmaceutical management.
- Technical support to MSH/RPM Plus activities with CAMERWA as needed.
- Debrief the USAID/Rwanda mission as requested

Activities

Brief USAID officials

The USAID/Rwanda mission did not request a briefing.

Provide technical support to Hare Ram Bhattarai, MSH/RPM Plus, who will be working in Rwanda in support of PEPFAR activities from September 12-24, 2004

Hare Ram Bhattarai traveled to Rwanda to provide technical assistance to the MSH/Rwanda staff in planning for the implementation of management information systems (MIS) for health care delivery in the context of ART activities, and in establishing monitoring and evaluation (M&E)systems for the same.

Since the MSH/Rwanda staff were new to both these technical areas (MIS and M & E) Mr. Bhattarai conducted short in-house sessions throughout his visit to orient the MSH/Rwanda technical staff in specifics of MIS and M&E for ART service delivery. Under PEPFAR activities. Onyango provided support and participated in the discussions during these sessions. These sessions covered:

- MIS implementing and strengthening activities carried out by RPM Plus/MSH in other countries
- Definitions and frameworks for MIS and M& E
- Demonstration of software developed in MS Access specifically for monitoring and evaluation of the ART program in Ethiopia and discussion this software could be adapted for use in health facilities in Rwanda

Mr. Bhattarai clarified for the staff that an essential component of RPM Plus/MSH work in strengthening these health facilities will involve ensuring that the records kept in the pharmacies and laboratories in these districts are relevant to program monitoring, as well as accurate and complete. This is because the information generated from these records provide the baseline and follow up information for monitoring the progress of the activities to strengthen commodity management in the ART program and evaluation of the program achievements at the end of the RPM Plus/MSH's involvement in the program. Good records allow for detection of problems early, so that solutions can quickly be identified and implemented.

The type of records in question are usually kept manually using paper forms, and should capture to data that includes: #patients served in the pharmacy, drug formulations and dosages dispensed, lab tests conducted, patient adherence to which patients, drug stock levels, expiry conditions of drug and commodity stock on hand, among others. Records can also be captured electronically, through use of computers.

Mr. Bhattarai emphasized that the RPM Plus/MSH work in MIS in Rwanda will focus on improving the process of what is being done in pharmacies and laboratories – in

particular, the flow of the process (is it rational and patient-centred) and the quality of the process. Patient flow for pharmacy and laboratory will need to be mapped out at each facility to determine areas needing intervention. Several indicators will be selected and monitored for each area of work, and each indicator should have a specific standard against which it will be measured. Indicators will be process, input and output indicators. The assessment to determine specific areas that need strengthening at each facility will need to be coordinated with partners working on clinical management at each facility.

Site visits to health facilities and district pharmacies

As part of its PEPFAR activities, MSH/RPM Plus will strengthen the pharmacy and laboratory aspects in 5 health facilities providing ART in Rwanda, and will also assist in strengthening commodity management in 2 district pharmacies. In August, 2004, the government of Rwanda assigned MSH/RPM Plus to coordinate with the Treatment and Research AIDS Center (TRAC) to work in the following facilities:

- Kicukiro Health Center, Province of Kigali Ville
- Biryogo Health Center, Province of Kigali Ville
- Ruhengeri District Hospital, Province of Ruhengeri
- Gihundwe District Hospital, Province of Cyangugu
- Butare University Hospital (Referral Hospital), Province of Butare

The government of Rwanda also assigned MSH/RPM Plus to coordinate with the Directorate of Pharmacy to strengthen the Ruhengeri and Kabutare District Pharmacies in Ruhengeri and Butare Provinces, respectively.

Mr. Bhattarai traveled to some of these assigned sites with Onyango and MSH/Rwanda staff as part of a preliminary assessment of the situation in facilities. Whilst MSH/Rwanda staff looked at a range of commodity management problems , Mr. Bhattarai assisted staff in looking at the specific MIS issues at these facilities. In general, facilities had varying methods for recording and reporting data, and key records did not exist at all in some pharmacies (such as patient-centred records and adherence data). Additionally, commodity management data were incomplete in several facilities. Mr. Bhattarai will provide a complete report summarizing his observations and his specific recommendations for intervention.

Onyango accompanied Mr. Bhattarai on visits to Biryogo and Kicukiro health centers. Mr. Bhattarai also visited Butare University Hospital, and Kabutare District Pharmacy with other RPM Plus/MSH staff.

Meetings with key stakeholders

Onyango also accompanied Hare Ram on visits with the following stakeholders who have particular interest in management information systems and monitoring and evaluation: Antoine Gatera, Senior Technical Advisor for the MSH office in Rwanda participated in

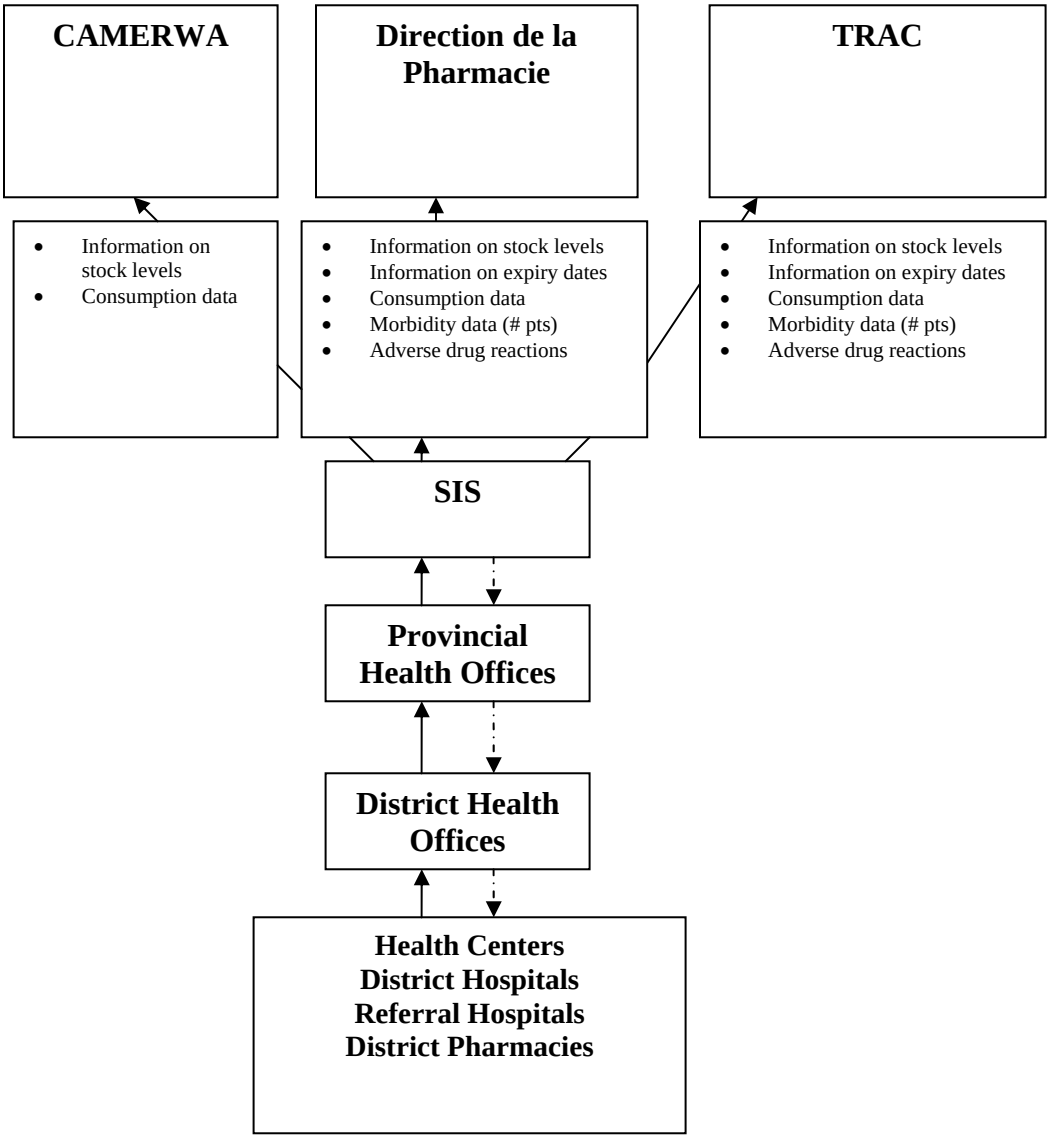
all the meetings. In the meeting with Dr. Claude Sekabaraga, Head of the Direction de Soins de Sante, the following points were discussed;

- It was clarified that MSH/RPM Plus plans to strengthen management information systems on two levels. One level is to help CAMERWA with its internal capture of data for decision making – this has been the focus of the work by RPM Plus consultant Andy Marsden. The other level is to improve the capture and quality of data at the facility level – this will the focus of the technical assistance by Hare Ram Bhattarai.
- It is a major priority of the DSS to ensure that data that is useful for decision making flows up the health system to SIS and other relevant stakeholders and data users.
- As RPM Plus/MSH proceeds with its work in strengthening MIS, it should be understood that when we talk of HIV/AIDS, this includes ART, OI drugs and STI drugs.
- Concern was expressed about the TRACnet system, since this does not strengthen the existing health information system, but instead bypasses it.
- RPM Plus/MSH should be aware that the Quality Assurance Project (QAP) has made available 15 lap tops to health centers to support PMTCT activities and another 15 laptops to support ART and PMTCT programs.
- ICT providers in Rwanda are establishing tele centers in rural areas and will fix satellite antennaes in rural hospital. As a result of these activities, Rwanda's public sector should soon have internet access in rural hospitals
- Each NGO in Rwanda is supposed to correspond to a Ministry or a Department within a Ministry. In general, health centers report/correspond to DSS. NGOs working on HIV/AIDS report/correspond to TRAC. Even though CAMERWA was created as an entity to be managed privately, it was created with government funds (revolving drug fund was started with World Bank funds) and is housed within building owned by the government. Technically, CAMERWA is supposed to report /correspond to the Department of Pharmacy within the Ministry of Health. It is important to understand and follow these relationships and chains of communication.

In the meeting with Mr. Védaste Munyankindi, Head of the Direction de la Pharmacie (DOP), the following points were discussed:

- It was clarified that the technical assistance from Hare Ram Bhattarai is focused on improving the capture and quality of data at facility level in support of the national ART program.
- DOP has three pharmacists at the moment, 2 persons with pharmacy training who did not finish school and 1 nurse and one non-technical staff person (total = 7 staff)

- At the moment, the DOP has two Divisions (Drug information and a Drug Inspectorate) and plans to create another Division (Drug Registration)
- The Drug Information department is supposed to create a national formulary for Rwanda (not done yet), create and update an essential medicines list (done) and create standard treatment guidelines for Rwanda (not done yet).
- DOP is not well integrated into the health management information system. For example the Système d'Information Sanitaire (SIS) receives information on tracer drugs through the HMIS, but DOP does not receive this information.
- To promote rational drug use, DOP does training, supervision of pharmacies. Supervision is done on a sample basis – once a year, they chose a province, and within that they chose a hospital and health center.
- Two studies have been done on the pharmaceutical sector by the Ministry of Health. One focuses on financial and geographic accessibility of drugs. The second is an indicator-based assessment on the performance of Rwanda's pharmaceutical sector. Unfortunately the second study is still in draft form, but it should be finalized soon. Védaste will provide this information on to indicators used in the second study to RPM Plus/MSH at a later date.
- The following set up was proposed by Mr. Bhattarai as being the best type of system to capture relevant health information data while involving all the relevant actors:



In the meeting with Dr. Emilien Nkusi, Système d'Information Sanitaire, the following points were discussed:

- The priority of the System d'Information Sanitaire (SIS) is to improve the quality of information collected from health facilities and transmission of information.
- There is a functioning health information system currently in place. Data is collected at the health facility level in forms and is sent up the health system – to District Health Offices, Provincial Health Offices and finally to the national office

of the SIS. At each level, the information is aggregated. SIS sends bulletin of feedback (indicators) to sites

- SIS reports the following indicators: World Bank PRSP indicators; EU indicators (Pays Pauvres Tres Endettées) and Rwanda national health indicators. Dr. Emilien will provide a list of the indicators reported on at a later date

- The new information system being proposed by Voxiva will have the health facilities transmitted information directly to TRAC (information will be accessible to partners such as CAMERWA, Global Fund, World Bank through some kind of password system) – the problem with this system is that it bypasses the existing health information system (District Health Offices, Provincial Health Offices and SIS at the national level).

- The existing TRACnet system does not appear to have a clear mechanism for taking corrective action once a problem is identified through information transmitted from health facilities. Whose responsibility is it to respond to information generated from TRACnet on stocks running low, for example? CAMERWA, TRAC? This is not clear.

- The entry of CAMERWA regional depots will complicate things even for the new TRACnet system

- TRAC should not be the hub of this information – rather, district health offices should be the hub of information so that District pharmacies can be made to respond. The information should continue to flow from health facilities and District Pharmacies up to District Health Offices, to Provincial Health Offices and finally to the national office of the SIS. Feedback should continue to flow from the National office at SIS down through the Provincial and District Health Offices to the health facilities, so that information can be used to make decisions.

- The major priority should be to integrate activities of TRACnet into the existing SIS, and to improve the quality and timing of data coming from health facilities – at the moment, 85% of the health centers report information to districts on time, and 52% of district hospitals report information to districts on time. Referral and private hospitals do not yet report their statistics to SIS.

- Health facilities should be brought together periodically by District Health Offices to share information on performance (which includes their performance with respect to ART).

- The next MIS forum will have to take place in early October, once the Director of Planning is back from leave. Dr. Nkusi will secure the Director's permission to begin planning this next forum.

Unfortunately, Mr. Bhattarai had to curtail his visit due to illness. However, he plans to return to Rwanda in mid to late October, 2004, to resume this work.

On September 22, Onyango also accompanied staff of preliminary assessment visits to Ruhengeri District Hospital pharmacy and laboratory and to Ruhengeri District Pharmacy.

Provide support to MSH/RPM Plus Rwanda staff for the organization of a stakeholder meeting to develop standard operating procedures (SOPs) for the pharmaceutical sector

On September 21, Onyango worked with RPM Plus/MSH staff to draft an agenda and logistical plan for a meeting to develop pharmaceutical management SOPs in support of Rwanda ART sites. The meeting is to take place during the second week of October. See the appendices for the draft agenda produced for the meeting.

Provide technical support to MSH/RPM Plus Rwanda staff for laboratory management and training activities

RPM Plus/MSH has been asked by the Government of Rwanda, USAID and the Centers for Disease Control (CDC) to coordinate a process to develop a national laboratory policy for Rwanda. To this end, Onyango worked with Charles Sasita, Program Associate in charge of laboratory activities for RPM Plus/MSH Rwanda to plan a stakeholder meeting to kick off this activity.

The following were completed:

Meeting on CD4 testing strategy for Rwanda

- Christine Onyango and Charles Sasita attended a meeting called by the National Reference Laboratory with other stakeholders on Rwanda national policy on CD4 testing. See Appendix 1 for the notes from this meeting.

Development of a national laboratory policy for Rwanda

- On September 23, Onyango and Sasita met with Emmanuel Rusangawa, Director of the National Reference Laboratories on September 22 to secure approval on proposed activities for national laboratory policy and to agree on date for first meeting. It is also an opportunity to find out more details about a meeting Rusanganwa had planned in October. Rusanganwa delegated the head of the National Public Health Laboratory – Mr. John Gatabazi –to work closely with MSH/Rwanda on this activity, as he is too busy to follow it. He declined to give approval or a tentative on the spot, instead opting to have another meeting the following week, by which time Mr. Gatabazi would have had time to review all relevant documents and check calendars for appropriate dates. This follow up meeting was there set for September 28. At these meeting, Rusanganwa shared that the meeting stakeholder meeting he had planned was on laboratory monitoring for ART programs and its aim was to educate stakeholders on all the elements of laboratory monitoring.

- In anticipation of this follow up meeting, Onyango and Sasita developed a draft agenda for the stakeholder meeting on developing a national laboratory policy – this draft would be discussed and refined with Gatabazi and Rusanganwa the following week. See Appendix 2 for this draft agenda.

- Sasita initiated a process of obtaining a calendar of activities for major laboratory related activities within Rwanda and in the African region to assist in planning for lab-related activities in the Rwanda ART program.

- Sasita initiated a process for obtaining background documents mentioned in paper on that should link to the national laboratory policy. Examples include the national health policy and the decentralization plan for the Ministry of Health. Sasita will liaise with Ministry of Health contacts and MSH/Rwanda staff to obtain these documents.

Development of generic laboratory standard operating procedures in support of the ART program in Rwanda

On October 8, RPM Plus/ MSH coordinated a stakeholder meeting to agree on an approach to develop generic laboratory standard operating procedures for ART activities at the facility level in Rwanda and to gather key background information to begin this activity. During the visit, Sasita produced a draft report on the meeting.

As a follow up,Onyango worked with Sasita to develop sub-activities for completing the development of national laboratory standard operating procedures. The following needs were identified to complete the activities, and a timeline was developed that incorporated all these elements (see Appendix 3 for this timeline and Appendix 4 for the meeting report prepared by Charles Rwabukera):

Needs for SOPs activity

People – ask Elisaphane and Rose to come on Wednesday Sept. 22 to determine whether to hire them for SOP activity
Scope of work for consultants – Charles to develop this
Contracts for consultant(s) – Charles to work with Antoine to finalize this
Copies of examples of SOPs -- from Kenya and from Rwanda **(Elisaphane)** as examples for consultants
Copies of meeting summary of Rwanda SOP meeting –Charles to finalize with help from Christine on the tables
Computer (s) for consultants to use in the office -- Charles will check on options for computer rentals
Reference books – WHO books are on the way, maybe Charles will need to order 2003 WHO book from Ikirezi and the Cheeseborough books……
Reviewers of draft SOPs -- Internal reviewers will be Catherine Mundy and Ephantus Njagi and external reviewers will be Dr. Wane (Butare Hospital) and Emmanuel Rusanganwa) – they need to be contacted, booked given appropriate codes and deadlines

Translator(s) for final SOPs – translation into English will be done of the draft SOPs developed by Elisaphane/Rose/Charles.
Consultants were identified and lined up and the process of contracting was initiated.

Provide technical assistance for the organization of training module on pharmaceutical management to be integrated into TRAC activities.

- MSH/Rwanda staff completed draft training modules for pharmaceutical management for review by Belén Tarrafeta, Team Leader for Rwanda with assistance. However, they identified the need to develop such a module for the laboratory and will discuss this further with Tarrafeta and Sasita.

Provide technical assistance in the revision of tools to assess capacity of ART sites for pharmaceutical management.

Several discussions occurred among Hare Ram and RPM Plus/Rwanda staff to discuss how to organize create, test and implement tools.

The following steps were agreed on for doing the facility readiness assessments:

- I. Make list of normative requirements and have this reviewed within office and outside office – for equipment and infrascture, classify info essential and less essential – Be sure to incorporate the normative standards laid out by TRAC and make sure that qualitative and quantative elements into the assessment tool
- II. Make a draft tool and have this reviewed internally and externally
- III. Test tool at one facility
- IV. Determine coordination with site partners (clinic staff, other PEPFAR partners) for the assessment
- V. Organize routing/make calendar for the assessment
- Deliverable: Draft tool for the Rwanda assessment?

Onyango and the RPM Plus/MSH team met with Laetitia, the pharmacist at TRAC, and Vedaste Munyankindi, Chief Pharmacist to discuss the following:

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- To define which are the standards for accreditation of Rwanda ART sites in order to ensure that RPM Plus/MSH site assessments take these into account
- Do clarify whether CNLS has any pharmathere is any mandate of CNLS in the used of indicators correspond to Pharmaceuticals management. (Laetitia)
- To define with TRAC and DOP who are the participants and the purpose of the meeting
- The dates and draft agenda for the planned meeting on developing pharmacy SOPs were discussed. New dates proposed were October 5 or 7. Some modifications were made to the agenda based on Laetitia and Védaste's

suggestions – mainly streamlining and not trying to squeeze many subjects into the meeting. See Appendix 5 for the draft agenda.

- Laetitia shared that in fact norms and standards for what should be in a pharmacy for ART has not yet been developed, as TRAC has focused on norms and standards for the clinic and clinical managment. Laetitia is happy to work with RPM Plus/MSH staff to develop these. It is possible that the Direction de Soins de Santé may have norms and standards for district hospitals – Védaste will check on these, as these norms would include norms for pharmacy and laboratory. Whatever information is found should be incorporated to the assessment tool for the pharmacy.
- CNLS has indicatorsrs, but Laetitia will find out if they have any pharmaceutical-related indicators

Technical support to MSH/RPM Plus activities with CAMERWA as needed.

No technical support was required from Onyango for these CAMERWA activities at this time.

Other activities

Additionally, CO accompanied STA to a meeting where instructions were given on how to complete the PEPFAR country operational plan for MSH for FY05. This information was transmitted back to MSH Country Team Leader for Rwanda Belen Tarrafeta, to complete documents by the deadlines given by USAID. See Appendix 6 for the presentation done by USAID as guidance.

Debrief the USAID/Rwanda mission as requested

The USAID mission requested a written summary rather than a debriefing meeting, since their schedules were too busy for an in-person meeting.

Appendix 1: Meeting on Rwanda National Policy and Coordination on CD4 testing

September 17, 2004

Minutes

Chair: Dr. Agnes Bingwaho, CNLS

Participants: Partners working in ART including: Family Health International (FHI) Global Fund, World Bank/MAP Centers for Disease Control, Médecins Sans Frontières, MSH, Elizabeh Glaser Pediatric AIDS Foundation (EGPAF), National Reference Laboratories, TRAC, Clinton Foundation, Botswana National Reference Laboratory (consultant to Clinton Foundation).

The purpose of the meeting was to discuss the various models for organizing CD4 testing in Rwanda and to share information on existing CD4 equipment in Rwanda and plans for purchase of additional CD4 equipment by various ART initiatives so as to coordinate laboratory testing activity and equipment purchase.

Mr Rusanganwa made a presentation on the state of CD4 testing in Rwanda. CD4 testing has seen a 200% increase within the past 8 months – 10, 384 CD4 tests have been carried out in Rwanda since January 2004. The National Reference Laboratory has 2 FACSCOUNT machines (capacity is to do 30 tests per day) and has a FACSCALIBUR machine on order (capacity is to do 300 tests per day).

Various ART initiatives within Rwanda have bought or plan to buy CD4 equipment. The World Bank MAP Project has purchased 3 FACSCOUNT machines for use in Cyangugu, Butare and Umutara Provinces. Other CD4 machines exist in Rwanda – a site run by MSF has a newly-purchased Partec Cyflow , and 2 Partec Cyflows are available at CHK (albeit basically non-operational due to numerous technical problems.

Rwanda will need the capacity to do between 180,000 to 200,000 CD4 tests by January 2005. After much discussion, meeting participants concluded that the current number of CD4 machines in Rwanda was sufficient to meet the requirement of up to 200,000 tests.

NRL has proposed a more centralized model of organizing CD4 testing than was originally envisioned by the Ministry of Health. In this model, specimens will be collected at ART sites and transported to the National Reference Laboratory for testing. Results will be returned to the sites. The previous decentralized model that was being proposed would have most of the CD4 testing done at peripheral sites (concentrated at referral and district hospitals).

Decentralization could reduce logistical problems associated with transporting samples across the country and increased time in reporting test results when samples are processed in Kigali. However, decentralization would also usher in difficulties in maintaining equipment (many machines to maintain across the country), would incur high costs in training and supervision of staff conducting tests in numerous sites, would require coordination of quality assurance for many sites, as well as coordination in procurement and management of laboratory reagents in many sites and so on. In short, decentralization of CD4 testing will be more complex and more costly to manage.

In his overview of the current state of CD4 testing in Rwanda, Mr. Rusanganwa reviewed currently CD4 technology available and the various pros and cons of each. Benefit/cost analysis was provided on four technologies – two of which are currently in use in Rwanda. Comparisons were also made on open vs. closed systems (open systems allow for reagents to be purchased from various sources), and rental vs.

outright purchase of the machine (rental may be more cost effective in the long run). Rusanganwa highlighted that one of the weakest points in the Rwanda's system of CD4 testing is data management which has bearing on whether doctors obtain lab results in a timely manner.

Since 3 FACSCOUNTS (lower throughput at 30 tests per day) have already been purchased and installed by the World Bank/MAP for use in strategic points around the country, the meeting participants voiced that this system should be implemented as originally intended. However, no more CD4 machines should be purchased for Rwanda.

However, meeting participants questioned whether this existing "network" of laboratory testing is functioning – not only for CD4 testing but also for key biochemistry and haematologtical tests to monitor toxicity for patients on ART. Dr. Agnes Bingwaho of CNLS asked that a meeting be convened by a sub group of the ARV committee to examine how well this system is functioning and whether there is equity in the current distribution of lab equipment for monitoring toxicity.

Meeting participants felt that the NRL should be concerned with coordinating the centralization of procurement of lab reagents (currently different ART initiatives in Rwanda have different arrangements) as well as the centralization of the maintenance of laboratory equipment and the coordination of data management as well as the transportation of samples throughout the country. Dr. Bingwaho tasked this sub group to also examine these issues and report back to the larger group with recommendations.

A suggestion was made that a spare FACSCOUNT be available at the NRL in Kigali to ship out to provinces in case one of the 3 FACSCOUNTs break down. However, a point was made that it is difficult to move a CD4 machine frequently without compromising its function and that moving the machine requires that a qualified technician accompany the replacement machine to install it correctly. A better solution would be to organize a referral system for CD4 samples that could function until the broken down machine in the province were fixed.

Mr. Rusanganwa announced his intention to call a meeting of stakeholders within the next 2 weeks to discuss the entire laboratory system for ART monitoring in Rwanda.

Dr. Bingwaho requested that NRL coordinate a meeting of the ARV subcommittee on the topics mentioned above that recommendations be provided within one week. Recommendations should be given to the larger committee within two weeks for how to coordinate laboratory monitoring of ARV toxicity.

Appendix 2: Draft agenda for meeting on creating a national medical laboratory policy for Rwanda

Opening of the meeting (Minister of Health)

Welcome and introductions: Director, NRL

Purpose of the meeting: To bring together key stakeholders to agree on the need for a national medical laboratory policy for Rwanda, and to come to consensus on an approach to draft and approve such a policy

Part I. Background

A. Presentation: What is a national medical laboratory policy and why does the health sector require one? (Director, NRL)

· **Definitions:** National Laboratory policy vs. guidance documents (equipment lists, lab accreditation requirements, etc) vs. National Laboratory Policy implementation plan

B. Presentation: Review of medical laboratory services and related policies in Rwanda (To be determined)

· Overview of medical laboratory services in Rwanda *(draw from Rwanda assessment)*

· Gaps in medical laboratory-related policy *(based on review of docs)*

· Other policies to consider (e.g decentralization of health services) *(based on review of docs)*

· Work on medical laboratory related policies to date: who is doing what in the Government of Rwanda and among technical assistance partners?

Part II. Creating a National Medical Laboratory Policy for Rwanda

A. Presentation: Process for developing and operationalizing a national laboratory policy – what approach should be taken by Rwanda? (To be determined)

· Proposed process for drafting policy (present draft action plan)

· Proposed process for review draft policy

· Proposed process for approval of draft policy

B. Moderated Discussion (Moderator to be determined)

C. Summary of consensus reached among stakeholders (Director, NRL)

D. Closing of the meeting (Secretary General, Minister of Health)

Appendix 3.: Sub-activities for preparing standard operating procedures for ART monitoring in Rwanda

Proposed sub-activities for preparation of laboratory SOPS for ART monitoring in Rwanda

	Timeline by Week										
Activity	**Sept 20-24**	**Sept 27-Oct 1**	**Oct 4-8**	**Oct 11-15**	**Oct 18-22**	**Oct 25-29**	**Nov 1-5**	**Nov 8-12**	**Nov 15-19**	**Nov 22-26**	**Nov 29-Dec 3**
Prepare report from Lab SOP workshop	X										
Identify consultants to develop lab SOPs	X										
Obtain and photocopy background materials for consultants including: Copies of Mombasa SOPs; copies of the workshop report; WHO reference materials and key lab textbooks	X	X									
Prepare scope of work for consultants	X										
Complete signing of consultant contracts		X									
Agree on format for SOPs	X										
Hire computer for consultants to use in the MSH office		X									
Contact internal reviewers (Mundy and Njagi)		X									
Conact external reviewers (Rusanganwa and Wane)		X									
Consultants and Charles prepare first draft of SOPS		X	X	X							
Translate first draft					X	X					
First draft to internal reviewers (Mundy and Njagi)							X				
Incorporate internal reviewer feedback								X			
Draft to external reviewers								X			
Incorporate external reviewer feedback and finalize second draft for stakeholder's workshop to review SOPs									X		
Send invitations and prepare logistics for workshop to review SOPS								X			
Stakeholder's workshop to get feedback on 2nd draft of SOPs										X	
Incorporate stakeholder feedback into SOPs											X

Appendix 4: Report from October 8 meeting on Developing Laboratory SOPs

Réunion avec les différents intervenants dans le domaine de laboratoire

Prepared by Charles Rwabukera, Program Associate, RPM Plus/MSH

Lieu : Hôtel des mille collines

Date : Le 08 Septembre 2004.

La réunion a été ouverte officiellement par le Secrétaire d'Etat chargé du VIH/SIDA et autres épidémies.
Monsieur Gatabazi Jean Baptiste , responsable du laboratoire national de santé publique et Directeur a l'intérim du NRL, est le seul représentant du Laboratoire National de Référence qui été présent, mais lui aussi n'a pas pu participer aux discussions ni au travaux en atelier parce qu'il a perdu sa mère la veille de la réunion.

Titre de la réunion : Processus de développement des protocoles standards de laboratoire pour le suivi biologique des patients sous ARV.

Objectifs de la réunion :

1. Apprendre les méthodes et les pratiques courantes utilisées au laboratoire

2. Obtenir l'information sur la diversité des méthodes utilisées dans nos laboratoires, la liste des équipements et réactifs

3. Identifier l'écart entre la liste des équipements existants dans nos laboratoires et celle élaborée (NRL, MAP et CDC) pour le suivi biologique des patients sous ARV.

4. Obtenir un consensus sur :
   - la liste des protocoles standards (SOPs) essentiels à développer
   - le mécanisme de développement et/ou de révision des protocoles
   - le processus d'approbation des protocoles à développer
   - le processus d'adaptation de ces protocoles

Programme du jour

8h30 : Enregistrement des participants

9h00 : Mot de bienvenu
Mr Gatabazi Jean Baptiste, Directeur a.i du Laboratoire Nationale de Référence

9h05 : Mot d'ouverture de la réunion,
Dr Nyaruhirira Innocent, Secrétaire d'Etat charge du HIV/ SIDA et autres épidémies

9h15 : Présentation de MSH,
Gatera Antoine, Conseiller Technique Principal de MSH/RPM Plus Kigali

9h30 : Situation actuelle des pratiques de laboratoire au Rwanda,

Gatabazi Jean Baptiste, Directeur a.i du Laboratoire Nationale de Référence

9h45 : Suivi biologique des patients sous ARV au Rwanda,
Sasita Rwabukera Charles, Program Associate, MSH/RPM Plus

10h00 : Bonnes pratiques de laboratoire,
Elisaphan Munyazesa, Enseignant au Kigali Health Institute

10h20 : Pause café

10h35: Discussions

11h05 : Répartition des membres en groupe de travail

11h15 : Travaux en atelier

13h00 : Déjeuner

14h00 : Travaux en atelier

15h00 : Plénière

16h00 : Conclusion et recommandations.

16h30 : **Clôture de la réunion**

Déroulement de la réunion

Apres le mot d'ouverture du Secrétaire d'Etat chargé du VIH/SIDA et autres épidémies, le Docteur Nyaruhirira Innocent, tous les exposés prévus ont été faits et les discussions ont été lancées.

Lors des discussions, certains aspects ont été soulignes :

- Il existe différentes méthodes, selon les laboratoires, qui sont utilisées pour effectuer différents tests de labo.
- Les protocoles standardises ont été longtemps souhaités par beaucoup d'intervenants en matière de laboratoire, pas seulement pour les tests en rapport avec le suivi ARV, mais aussi pour tous les autres testes utilisés dans les services de laboratoire du pays.
- Le LNR doit renforcer sa collaboration avec les laboratoires des hôpitaux de référence, car actuellement cette collaboration parait inexistante. Ceci car les différentes décisions concernant les politiques du LNR en rapport avec certains aspects ne sont souvent pas communiquées au niveau des laboratoires des hôpitaux de référence.

Méthodologie utilisée

Apres les discussions en rapport avec les exposes, nous avons constitue trois groupes de travail en atelier. Les groupes de travail ont été constitués de sorte qu'on retrouve dans chacun un représentant du laboratoire de centre de santé, un représentant du laboratoire du district et un représentant du laboratoire de l'hôpital de référence. Comme la plupart des tests faits en rapport avec les ARV sont en général du domaine de l'hématologie et de la biochimie :

- le premier groupe a traite des questions relatives aux tests hématologiques
- le deuxième groupe a traite des questions relatives aux tests biochimiques
- le troisième groupe a traite des différents aspects en rapport avec la qualité des analyses en général et la sécurité au laboratoire.

Apres les travaux en groupe, un rapporteur par groupe a partagé avec les autres participants en plénière sur les aspects suivant du questionnaire distribué dans les groupes :

- les problèmes qui surviennent souvent lors de l'introduction des nouveaux tests dans nos laboratoires
- les souhaits des membres du groupe en rapport avec l'introduction des nouveaux tests dans les différents laboratoires
- leurs conclusions sur le besoin de standardiser ou pas les protocoles de laboratoire en rapport avec le suivi des patients sous ARV tout en signalant les avantages et inconvénients de cette standardisation.

Resultats :

Certains laboratoires ont déjà introduit des nouveaux tests et ont eu comme problèmes :

- organisation des approvisionnements
- formation du personnel en techniques nouvellement introduites
- formation du personnel en maintenance des équipements
- infrastructures limités
- quantité de travail augmenté sans augmentation du nombre de personnel d'où surcharge des techniciens
- problème de conservation des réactifs
- pour certains tests (méthodes manuelles en hématologie) ces protocoles existent et ont été développés par l'OMS ; pour d'autres ces protocoles n'existent pas.

- Avantages de la standardisation des protocoles

- Facilite d'exécution des tests
- Facilite de contrôle de qualité
- Résultats sont plus reproductibles et plus fiables
- Facilite dans la supervision des laboratoires et même dans la collaboration entre les laboratoires
- Facilite dans l'approvisionnement en réactifs et consommables de laboratoire
- Facilite dans la maintenance préventive et curative des équipements
- Facilite dans la rotation des techniciens d'un service à un autre
- Facilite dans la formation du personnel et celle des étudiants

- Inconvénients de la standardisation :

* le risque de ne pas avoir assez de connaissances sur les autres méthodes utilisées au laboratoire autres que le sien.

Conclusion générale :

Apres les discussions et échanges entre les membres des différents groupes, les participants en plénière se sont mis d'accord que :

- les méthodes, les équipements et les réactifs qui sont utilises dans nos différents laboratoires sont très varies et dépendent d'un laboratoire a un autre.

- Le contrôle de qualité des tests qui sont faits au niveau du pays est difficile a faire étant donnée cette diversité des méthodes, équipements et réactifs actuellement utilises.
- tous les trois groupes de participants sont d'accord qu'il faut standardiser les protocoles utilisés dans nos de laboratoire car les avantages de la standardisation des protocoles sont plus nombreux que ses inconvénients.

Recommandations :

- Les participants proposent que le LNR rédige un draft des protocoles standards
- Ce draft devra être partagé avec les autres partenaires intervenants dans le domaine de laboratoire pour commentaires et corrections avant de produire le document final.
- les participants ont demandé que les techniciens et les gestionnaires des laboratoires soient tous impliqués dans ce processus afin de donner leurs différentes contributions au développement des protocoles standards pour qu'ils appropriés à nos laboratoires c'est -a- dire réellement applicables dans nos laboratoires. L'utilisation de cette procédure réduirait au maximum la probabilité de glisser des erreurs dans différents protocoles et impliquerait toutes les catégories d'intervenants car ils devront tous contribuer a l'utilisation de ces protocoles.
- Avant l'adoption définitive de ces protocoles standards, ils devront d'abord être testées dans certains laboratoires pour voir s'ils sont réellement pratiques dans nos laboratoires.
- Les protocoles standards qui seront rédigés devront être revus chaque année.
- Les participants souhaitent que les nouveaux achats des équipements pour les nouveaux sites se conforment aux équipements déjà présents aux autres sites de même niveau afin de standardiser aussi les équipements.
- Les participants souhaitent que les risques encourus par les techniciens de laboratoires en matière de HIV soient reconnus et demandent qu'une politique de compensation de ces risques soient mis en place.
- Les participants ont émis le souhait d'avoir une liste officielle des tests recommandées pour le suivi des patients sous ARV a chaque niveau de structure de santé (centre de santé, hôpital de district et hôpitaux de référence).
- Les participants ont demandé que le développement des protocoles standards soit accompagnés par :

    - des formations sur l'utilisation de ces protocoles standards
    - des formations en gestion de stock des réactifs de laboratoire
    - des formations continues en techniques de laboratoire en général et en techniques nouvellement introduites dans chaque laboratoire en particulier
    - l'exigence de l'introduction des contrôles de qualité interne dans chaque laboratoire
    - l'organisation des contrôles de qualité externe par le laboratoire national de référence avec feed-back aux laboratoires de district
    - des supervisions plus fréquentes des techniciens qui sont sur terrain au niveau périphérique par le laboratoire national de référence
    - l'établissement des normes de travail : volume de travail par technicien et par jour

Appendix 5: Draft agenda for meeting on developing standard operating procedures for the pharmaceutical management in Rwanda ART programs

Purpose of the meeting:

- To explain and convince on the need for SOPs for the pharmacy
- To get stakeholders to identify which SOPs are necessary for the pharmacy (use flow diagram)

Agenda (Draft)

8:20 am ***Opening*** by DOP
8.30 am ***Introduction*** by Antoine Gatera (10 min max)
9.00 am ***Presentations***

1. **MSH/RPM Plus** - what SOPS are and how they assist with pharmaceutical management (10 min)

2. **TRAC** - Presentation on accreditation requirements for pharmacy for Rwanda ART program (10 min)

3. **DOP**- Presentation on their role in commodity management in health facilities (10 min)

9.40 am *Questions/ Answers and Clarification* (20 min
10.00 am *Break* (10 min)

10.15am **3 Presentations by RPM Plus sites**- what is happening with respect to commodity management (10 min each presentation)

The Butare University Hospital , Ruhengeri hospital and Kicukiro Health center were proposed to do that because they are quite better organized.

Questions /Answers and Clarification (30 min)

11:15 am – 12:15 pm ***Working groups***

Working Group (I)
- Requisition to receipt of products

Working Group (II)
- Stock management : issues to dispensing pharmacy to distribution of patients

Working Group (III)
- Adherence tracking and ADRs

12:15pm – 1:15 pm Lunch ***time***

1:15 -2:20 pm ***working groups*** (suite)
Working groups resume for one hour
2.20-3.30 pm Working groups summarize discussions and present SOPs lists to plenary (20 min x 3 groups)
3.45 pm Last questions and comments (15 min)
4.00 pm Summary and next steps (30 min)

- To agree on methodology, sequence and timing for developing
- To agree on process for approving and introducing SOPs in sites
- To agree on mechanism for reviewing SOPs

4.30 pm Close

Liste des institutions à inviter dans la réunion sur le Développement des Procédures Standards en Pharmacie
Kigali- Hôtel des Mille Collines -08/10/2004-

	Institution	Participant	Adresse
1	Hôpital de Gihundwe	Ngabo Hesron	08790544
2		Virginie	08773050
3	CHU/CHB	Noël Rutambika	08492585
4		Pharmacy dispensation	…….....
5	District de Kabutare	Pharmcy stock	…….....
6	Centre de Santé de Biryogo	Pharmcy stock	08479874
7		Pharmacy dispensation	……
8	Centre de Santé de Kicukiro	Pharmcy stock	586073….
9		Pharmacy dispensation	…….
10	Hôpital Ruhengeri	Pharmcy stock	08487478
11		Pharmacy dispensation	08472278
12	District de Ruhengeri	Jeannette N. bari	08690259
13	TRAC/ MAP/ MCUP	Laetitia Uwineza	08558759
14		Denyse Murekatete	08408285
15	Direction de la Pharmacie	Vedaste Munyankindi	08530949
16		Alexis Ruzindaza	08830540
17	CAMERWA	Aline Mukerabiroli	……..
18	OMS	Stella Tuyisenge	08410477
19	Deliver	Technical Assistant	08307602
20	DSS	Dr Bonaventure Nzeyimana	08585815
21	FHI	Dr Martin ou Fabienne	…….
22	Global Found	Dr Anicet Nzabonimpa	…….....
23	Lux- Development	Christine Omes	…….....
24	CHU/CHK	Tayari J.Claude	08417757
25		Dr Mfizi jean	
26	HMK	Ernest Kalisa	
27		Léon Ruvugabigwi	08597162
28	MSF	Dr J. Pascal	
29	Care International	…….	……

Appendix 6: Guidance presented by USAID/Rwanda on how to prepare FY05 Country Operational Plans

USG-Rwanda
PEPFAR Country Operational
Plan 2005

Requirements, Process and
Timelines for Implementing
Partners

Outline of Meeting

- New PEPFAR Results and Expectations
- Process of compiling COP
  - One-page project proposals
  - Partner Activity Document
- COP information requirements: Partner Activity Document
  - Section 1
  - Section 2

PEPFAR Results and Expectations

- List of sample results (developed by OGAC) found in Appendix of Activity Document
- Results show significant shift in focus from merely 2-7-10 goals to emphasis on system strengthening
- Partners should consider sample results when designing new proposals and scale-up of existing projects

Timeline for COP document submission

- September 17: One-page project proposals due to USAID. Will be reviewed quickly and returned with comments
- September 27: First Draft of Activity Document due to Agency
  - Activity document draft should be informed by one-page proposals and comments
- October 15: Full draft of USG-Rwanda COP due
- October 29: Final copy of USG-Rwanda COP due to Washington

Structure of FY05 COP

- Submitted to Washington through database
- Components:
  1. Country Program Strategic Overview (USG, will draw directly from 5 year strategy)
  2. Prevention, Care and Treatment Targets (Assigned and generated by USG and partners)
  3. **USG Country Plan**
  4. Summary Budget Table (compiled from information in section 3)
  5. Planned Data Collection (by all Donors and GOR) in Countries

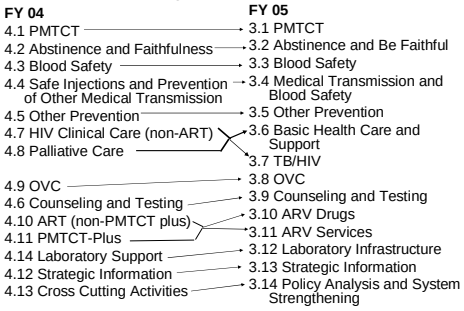
Partner Activity Document

- To the largest extent possible, the Activity Document contains the information that is needed from partners for FY05 COP
- Meant as a tool to:
  1. Inform and engage partners on information that is needed for FY05 COP
  2. Assist USG team in program planning, monitoring and identifying gaps in current program and proposals
  3. Ease program planning and reporting requirements in the future by consolidating information into one document that reflects trends and scale-up.
- FIRST DRAFT of Activity Document requested from partners on September 24.

Activity Document Section 1: General Partner Project Information

- Tables ask for basic information about mechanism, prime partner and sub-contracts
- Budget information for all program areas in which a partner works for FY04 (PMTCT, Track 1, 1.5 and 2) and FY05 proposal
- Section 1 needs to be filled out only ONCE for each agreement
- These tables correspond to Tables 3.1 and 3.2 of the COP.

PEPFAR Program Areas: FY04 vs. FY05



Activity Document Section 2: Program Area Data

- Corresponds to Table 3.3 (Program Planning Table) and is the heart of the COP
- Section 2 is divided into the 15 program areas
- Partners need only submit Section 2 tables for program areas in which they operate.
- Information is not divided by activity or expected result (as in FY04 COP) but by funding mechanism
- Targeted program evaluations should be included in the appropriate program area (not Strategic Information), unless the evaluation cuts across several areas

Section 2 Data Requirements: Activity Table

- Asks for approximate percentages of program area funding by type of activity (i.e. training, human resources, policy guidelines, etc)
- This is a new way of looking at budget and program information
- Data will primarily be used by O/GAC for reporting to Congress
- Information potentially useful for program planning and identifying priorities

Section 2 Data Requirements: Program Area Narrative

- Each mechanism should have ONE narrative for each program area in which you work
- Narrative should address activities under that program area that will be undertaken or are proposed in FY05
- Narrative should include 3-5 targets the activities will achieve. These targets will be negotiated with the USG team in collaboration with the 5-year strategy development

Section 2 Data Requirements: Planning and Fiscal Year Targets

- Targets requested at 6-month intervals for both FY04 (PMTCT, Track 1.0, 1.5 and 2.0) and FY05 funding:
  - April 1, 2004 – September 30, 2004 (actual results)
  - October 1, 2004 – March 30, 2005 (ongoing activities with FY04 funds)
  - April 1, 2005 – September 30, 2006 (FY05 funds proposed)
  - October 1, 2005 – March 30, 2006 (FY05 funds proposed
- Will help monitor success and scale-up of program over time
- Gathers reporting data for both fiscal year and programmatic year
- Estimate of results by direct and indirect USG support

Target Populations, Special Focus Areas and Geographic Location

- Select target populations of activities within program area from list provided
- Note any of list of special focus areas that are addressed by activities
  - i.e. empowerment of women, reducing violence and coercion
- Indicate geographic location of activities